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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,239	02/23/2000	LORNA FYFE	013455.00001	3544

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EXAMINER

PATTEN, PATRICIA A

ART UNIT

PAPER NUMBER

1654

22

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/486,239

Applicant(s)

Fyfe, L.

Examiner

Patricia Patten

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 21, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 11, and 14-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 11, and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

RCE Practice

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 10/21/02 has been entered.

Claims 10-11 and 14-19 are pending in the application and were presented for examination on the merits. Claims 14 and 15, previously drawn to the non-elected invention, are now drawn to the elected invention via amendments made on 10/21/02.

Claim Objections

Claim 11 is objected to because of the following informalities: Claim 11 recites 'wherein the concentration of concentration of benzoic acid...' Which is grammatically

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redundant. It is thought that Applicant intends for this to recite 'wherein the concentration of benzoic acid....', and thus, it is suggested that the second instance of 'concentration of' be deleted in order to overcome this objection .

Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claim 11 recites 'paraben' while claim 10 recited specific species of paraben such as methyl paraben and propyl paraben. Thus, claim 11 broadens rather than limits claim 10. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding claim 10, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purohit et al. (US 4,966,754). Claims 10, 14, 16 and 18 are drawn to a composition comprising a plant oil such as fennel oil or basil oil, or an active component thereof such as trans-anethole, fenchone or estragole, in combination with benzoic acid or a paraben such as methyl paraben, wherein the formulation is admixed with a pharmaceutically acceptable carrier, wherein the medicament inhibits micro-organism growth, and wherein the formulation is in the form of a spray.

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Purohit et al. (US 4,966,754) taught compositions for preserving cosmetics (Abstract). Purohit et al. taught that methyl and propyl paraben were well known bacteriocidal (toward *S.aureus*) and non-toxic preservatives found in cosmetics (col.1, lines 18-23). Purohit et al. taught that many essential oils, such as basil oil, Fennel sweet oil and active components of essential oil such as estragon (a.k.a., estragole) were antimicrobally effective toward *A. Niger*, *C.albicans*, *S.aureus* and *P.aeruginosa* (col.1, lines 37-64 and col.2, line 62- col.3, line 35/ See 'Table'). Purohit et al. further taught that the preferred amount of essential oil or component thereof should have been present in the composition from 2-5%, while 2% was preferred (col.3, lines 43-47). Purohit et al. disclosed that cosmetics "require[ed] a dermatologically acceptable carrier or vehicle" (col.2, lines 45-50).

Where claim 16 recites 'a medicament to inhibit micro-organism growth' is intended use language which does not materially change the composition. It is noted that the term 'medicament' is a broad term. The Examiner has interpreted 'medicament' to mean any agent which has the potential of exhibiting even a small degree of pharmaceutical benefit. In the instant case, either of methyl paraben or basil oil would possess some medicinal benefit because both inhibited microorganisms which were known in the art to have virulent capabilities such as *S.aureus*. Therefore, the individual constituents would have constituted 'medicament' which inhibited microorganism growth.

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Additionally, claim 18 recites 'spray formulation'. The Examiner has given the term it's broadest interpretation, and deemed that any liquid could be sprayed (i.e., placed in a spray bottle and 'sprayed'). Thus, it appears that this claim limits claim 11 to wherein the composition is in liquid form. It is deemed that the essential oils such as basil oil and fennel sweet as disclosed by Purohit et al. were in liquid form and therefore could have been 'sprayed'.

Purohit et al. did not specifically teach a specific combination of basil oil along with preservatives such as methyl or propyl paraben further in combination with a carrier.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each was well known in the art to possess bacteriocidal activity toward *S.aureus*, thereby rendering these constituents as suitable cosmetic preservatives according to Purohit et al. One of ordinary skill in the art would have been motivated to combine antimicrobial agents such as basil oil and methyl paraben for example, in a cosmetic composition in order to achieve an additive bactericidal effect. The ordinary artisan would have been further motivated to have added a carrier base in order to have formulated a cosmetic composition which could have been easily applied by the

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consumer. As stated *supra*, Purohit et al. Taught that carriers were 'required' when producing cosmetics.

This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Claims 10-11 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purohit et al. (US 4,966,754) in view of Zimmerman et al. (US 5,443,817). The nature of claims 10, 14, 16 and 18 were discussed *supra*. Claims 11, 15, 17 and 19 are further drawn to wherein the concentration of benzoic acid or paraben is from 0.01% to 1%, wherein this composition is admixed with a pharmaceutically acceptable carrier, wherein the medicament inhibits micro-organism growth, and wherein the formulation is in the form of a spray.

The teachings of Purohit et al. were discussed *supra*, which provided motivation for the combination of oils such as basil oil with preservatives such as propyl paraben to inhibit microorganism growth.

Purohit et al. did not mention wherein an acceptable concentration of methyl or propyl paraben was from 0.01% and 1% of the composition, nor where this particular

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composition was combined with a pharmaceutically acceptable carrier or wherein the medicament was 'to inhibit micro-organism growth' or wherein the formulation was in the form of a 'spray formulation.'

Zimmerman et al. (US 5,443,817) taught a sprayable cosmetic cleansing formulation which contained preservatives such as propyl paraben for protection against microbial contamination (Abstract and col.4, lines 43-62). Zimmerman et al. proposed that "Preservatives are preferably employed in amounts ranging from about 0.01% to about 2% by weight of the composition" (col.4, lines 60-62).

It would have been obvious to combine basil oil and propyl paraben in a cosmetic carrier as discussed *supra*.

One of ordinary skill in the art would have been motivated to have incorporated the propyl paraben in an amount from 0.01% to about 2% into a cosmetic composition comprising a bacteriocidal essential oil such as basil oil in order to afford an effective amount of preservation potential. The ordinary artisan would have had a reasonable expectation that the combination of basil oil and the preferred concentration of preservative would have afforded good protection against bacterial contamination, which would have in turn produced a cosmetic product which was safer for consumers.

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It is noted that 0.01%-2% (disclosed range) overlaps with the claimed range of 0.01%-1%. Thus, the claimed range is obviated by the range as disclosed by Zimmerman et al. (See MPEP § 2144.05).

Where claim 16 recites 'a medicament to inhibit micro-organism growth' is intended use language which does not materially change the composition.

Additionally, claim 18 recites 'spray formulation'. The Examiner has given the term it's broadest interpretation, and deemed that any liquid could be sprayed (i.e., placed in a spray bottle and 'sprayed'). Thus, it appears that this claim limits claim 11 to wherein the composition is in liquid form. It is deemed that the essential oils such as basil oil and fennel sweet as disclosed by Purohit et al. were in liquid form and therefore could have been 'sprayed'.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

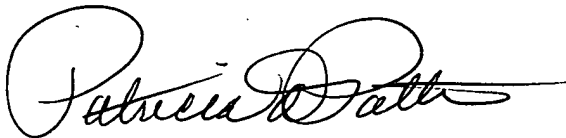
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

11/18/02

A handwritten signature in cursive script, appearing to read "Patricia Patten", with a long horizontal flourish extending to the right.